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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/716,146	11/17/2000	Christopher T. Boyle	6006-018	6734

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EXAMINER
MILLER, CHERYL L

ART UNIT	PAPER NUMBER
3738	

DATE MAILED: 05/17/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/716,146	Applicant(s) BOYLE, CHRISTOPHER T.	
	Examiner Cheryl L. Miller	Art Unit 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondenc address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 November 2000* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *17 November 2000* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Information Disclosure Statement

1. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Specification

1. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

Line 1 of the abstract contains the phrase "The present invention", which is improper and should be deleted.

Drawings

2. The drawings are objected to because the actual drawing lines and reference numerals are light, unclear and difficult to read. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

3. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference characters "47" on pg.10, line 9 and "49" on pg.10, line 14, have both been used to designate bioactive agent. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

4. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character "47" has been used to designate both internal cavity and bioactive agent on pg.10, line 9. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance. It is suggested to change "47" to --49-- on pg.10, line 9.

5. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference sign(s) not mentioned in the description: reference sign (39) in fig.6 and reference sign (32) in fig.5. A proposed drawing correction, corrected drawings, or amendment to the specification to add the reference sign(s) in the description, are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

6. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: x, y, and z axis are not labeled in fig.8. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 3-7, and 9-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 4, 7, 10, and 14 are Markush type claims and should recite the language --selected from the group consisting of--. It is suggested to change "selected from the group of" to recite --selected from the group consisting of--.

9. Regarding claims 3, 6, 9, and 13, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

10. Claim 5 recites the limitation "proximal or distal end" in line 7. There is insufficient antecedent basis for this limitation in the claim. Claims 6-7 depend on claim 5 and inherit problems associated with the parent claim.

11. Claims 6 and 9 recite the limitations "The implantable body" and "the structural body" in line 1 of both claims. There is insufficient antecedent basis for these limitations in the claims. It is suggested to change "The implantable body" to recite --The endoluminal stent--, and to change "the structural body" to recite --the tubular member--.

12. Claims 7 and 10 recite the limitation "The implantable body" in line 1. There is insufficient antecedent basis for this limitation in the claims.

13. Claim 11 contains language in lines 3-5 that is unclear as to what exactly is being claimed. Claims 12-14 depend upon claim 11 and inherit all problems associated with the parent claim.

14. Claim 13 recites the limitation "The implantable body" in line 1. There is insufficient antecedent basis for this limitation in the claim.

15. Claim 14 recites the limitation "The implantable body" in line 1. There is insufficient antecedent basis for this limitation in the claim. It is suggested to change "The implantable body" to recite --The endoluminal stent--.

Claim Rejections - 35 USC § 102

16. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

17. Claims 1-11 and 14 are rejected under 35 U.S.C. 102(e) as being anticipated by Brown et al. (USPN 6,071,305). Brown discloses an endoluminal stent, which includes all limitations recited in the claims. Referring to claims 1, 5, and 8, Brown discloses an implantable endoluminal stent (11) having a 3-D, tubular structure comprising a plurality of structural elements and a thickness (col.1, lines 15-16; fig.2, 18). Brown discloses at least one internal cavity (20) in the thickness of each structural element (fig.18), a plurality of openings (22), (fig.6) communicating between a cavity and a surface external the stent (col.2, lines 59-65), and at least one bioactive agent (23). Referring to claim 8, Brown discloses interior cavities that may be discontinuous (fig.18; col.5, lines 50-55; col.6, lines 15-21). Referring to claim 11, Brown discloses a tubular member having a recessed portion to receive an active agent, wherein the recess has a depth less than a thickness of a tubular member (col.3, lines 35-45). Referring to claims 3, 6, and 9, Brown discloses the tubular member or structural body comprises a material selected from the group claimed (col.7, lines 12-19). Referring to claims 4, 7, 10, and 14, Brown discloses a bioactive or active agent selected from the group claimed (col.5, lines 1-27).

18. In the alternative to the above rejection, claims 11 and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Williams (USPN 5,707,385). Williams discloses an endoluminal stent, which includes all limitations recited in the claims. Williams discloses an endoluminal stent for delivering a bioactive agent (col.2, lines 17-29) comprising a plurality of structural elements and lumens forming a

cylinder (16), (fig.8, 8A), a plurality of tubular members (90), (5), (fig.9) having a recessed portion (91) for receiving a bioactive agent (fig.12; col.11, lines 7-11), the bioactive agent being one as claimed in claim 14 (col.6, lines 6-41).

Claim Rejections - 35 USC § 103

19. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

20. Claims 12-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brown in view of Alt (USPN 6,099,561 B1). Brown discloses an endoluminal stent substantially as claimed. Brown does not disclose however, a stent fabricated by vapor deposition of at least one metal. Alt teaches in the same field of endeavor, an endoluminal stent (col.1, lines 14-16) fabricated by vapor deposition (col.9, lines 2-25) of at least one metal (col.7, lines 44-52) for the purpose of preventing cracking, peeling or flaking of the metal layer. It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine Alt's teaching of fabrication method, with Brown's endoluminal stent in order to prevent cracking, peeling, or flaking of a stent.

21. In the alternative to the above rejection, claims 12-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brown in view of Reed et al. (USPN 6,197,013 B1). Brown discloses an endoluminal stent substantially as claimed. Brown does not disclose however, a stent fabricated by vapor deposition of at least one metal. Reed teaches in the same field of endeavor, a stent fabricated by vapor deposition (col.9, lines 42-67) of at least one metal (col.11, lines 27-38) for the purpose of depositing a desired stent pattern. It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine Reed's teaching of fabrication method, with Brown's endoluminal stent, in order to fabricate a stent with a desired pattern.

Conclusion

22. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

USPN 6,096,175 to Roth discloses a fabrication process for a stent that includes motivation for making a stent with a specific pattern.

USPN 5,772,864 to Moller discloses a description of a vapor deposition method.

USPN 6,240,616 B1 to Yan discloses an endoluminal stent having cavities and pores that carry medication within.

USPN 5,716,340 to Schweich, Jr. et al. discloses a delivery catheter having cavities and holes connecting cavities to a vessel wall to deliver a drug, the features related to claim 1.

USPN 6,273,908 B1 to Ndondo-Lay discloses an endoluminal stent having holes or recesses to hold a drug, the features related to claim 11.

USPN 5,370,681 to Herweck et al. discloses an implantable body having a plurality of lumina or channels to hold a drug, the features related to claims 1 and 5.

USPN 5,411,550 to Herweck et al. discloses an implantable body having cavities and connecting pores for a bioactive agent to diffuse from body into bloodstream, the features related to claims 1 and 5.

USPN 5,972,027 to Johnson discloses a stent having pores that contain drugs, the features related to claim 11.

USPN 6,379,381 B1 to Hossainy et al. discloses an endoluminal stent having interconnected structural elements, the elements having cavities with holes connecting cavities to a vessel wall, and therapeutic substances contained within the cavities, the features related to claims 1, 5, 8, and 11.

USPN 6,206,915 B1 to Fagan et al. discloses continuous or discontinuous cavities and holes connecting cavities to vessel lumen and wall, the features related to claims 1, 5, and 8.

USPN 6,358,276 B1 to Edwin discloses a stent having one continuous cavity and holes or pores connecting cavity to a vessel wall or lumen, the features related to claims 1-3, 5, and 6.

USPN 6,254,632 to Wu et al. discloses a stent having recessed portion to carry a bioactive agent, also having a porous graft, the features related to claim 11.

USPN 6,273,913 B1 to Wright et al. discloses a stent having holes or recesses in struts for carrying a specific drug, the features related to claim 11.

USPN 4,309,776 to Berguer discloses an implantable body having a chamber and pores connecting chamber to vessel wall and lumen.

USPN 3,796,217 to Arlen discloses a drug delivery system having a chamber and holes connecting chamber an exterior, the system carrying a specific drug.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cheryl L. Miller whose telephone number is (703) 305-2812. The examiner can normally be reached on Monday through Friday from 7:30am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached on (703) 308-2111. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3590.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

Cheryl L. Miller
05/13/2002

CORRINE McDERMOTT
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700

Attachment for PTO-948 (Rev. 03/01. or earlier)
6/18/01

The below text replaces the pre-printed text under the heading, "Information on How to Effect Drawing Changes," on the back of the PTO-948 (Rev. 03/01, or earlier) form.

INFORMATION ON HOW TO EFFECT DRAWING CHANGES

1. Correction of Informalities -- 37 CFR 1.85

New corrected drawings must be filed with the changes incorporated therein. Identifying indicia, if provided, should include the title of the invention, inventor's name, and application number, or docket number (if any) if an application number has not been assigned to the application. If this information is provided, it must be placed on the front of each sheet and centered within the top margin. If corrected drawings are required in a Notice of Allowability (PTOL-37), the new drawings MUST be filed within the THREE MONTH shortened statutory period set for reply in the Notice of Allowability. Extensions of time may NOT be obtained under the provisions of 37 CFR 1.136(a) or (b) for filing the corrected drawings after the mailing of a Notice of Allowability. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

2. Corrections other than Informalities Noted by Draftsperson on form PTO-948.

All changes to the drawings, other than informalities noted by the Draftsperson, MUST be made in the same manner as above except that, normally, a highlighted (preferably red ink) sketch of the changes to be incorporated into the new drawings MUST be approved by the examiner before the application will be allowed. No changes will be permitted to be made other than correction of informalities, unless the examiner has approved the proposed changes.

Timing of Corrections

Applicant is required to submit the drawing corrections within the time period set in the attached Office communication. See 37 CFR 1.85(a).

Failure to take corrective action within the set period will result in ABANDONMENT of the application.